

PATENT COOPERATION TREATY

25 NOV 2004

PCT

From the INTERNATIONAL SEARCHING AUTHORITY

To:

GLAXOSMITHKLINE
Corporate Intellectual Property
Attn. Pritchard, Judith
980 Great West Road, (CN925.1)
Brentford
Middlesex TW8 9GS
UNITED KINGDOM

Received
NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

GlaxoSmithKline
Corporate IP
Received BRENTFORD
24 NOV 2004
ATTY CHECKED/FILE
DATE 24/11/04
FOR FURTHER ACTION

(PCT Rule 44.1)

Applicant's or agent's file reference

JXP-PB60390

Date of mailing
(day/month/year)

24/11/2004

International application No.

PCT/EP2004/007819

International filing date
(day/month/year)

09/07/2004

Applicant

GLAXO GROUP LIMITED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Eva Boháčová

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference JXP-PB60390	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/EP2004/007819	International filing date (day/month/year) 09/07/2004	(Earliest) Priority Date (day/month/year) 11/07/2003
Applicant GLAXO GROUP LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the title,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

SPECIFIC GLUCOCORTICOSTEROID COMPOUND HAVING ANTI-INFLAMMATORY ACTIVITY

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the drawings,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/007819

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07J3/00 A61K31/56 A61P5/44 C07D239/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07J A61K C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 02/00679 A (NOVARTIS ERFIND VERWALT GMBH ; NOVARTIS AG (CH); BEATTIE DAVID (GB); C) 3 January 2002 (2002-01-03) page 9, paragraphs 3,4 claim 1	1-22
A	GB 1 514 476 A (GLAXO LAB LTD) 14 June 1978 (1978-06-14) claim 1	1-22
A	US 3 856 828 A (PHILLIPPS G ET AL) 24 December 1974 (1974-12-24) column 1, lines 1-5 claim 1	1-22
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

17 November 2004

Date of mailing of the international search report

24/11/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040. Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Samsam Bakhtiary, M

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2004/007819

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>UENO H ET AL: "Synthesis and evaluation of antiinflammatory activities of a series of corticosteroid 17.alpha.-esters containing a functional group" JOURNAL OF MEDICINAL CHEMISTRY, AMERICAN CHEMICAL SOCIETY. WASHINGTON, US, vol. 34, no. 8, 1 August 1991 (1991-08-01), pages 2468-2473, XP002086576 ISSN: 0022-2623 abstract page 2470; table II compound 131</p>	1-22
A	<p>----- WO 89/03390 A (BODOR NICHOLAS S) 20 April 1989 (1989-04-20) page 1, lines 1-8 claim 1</p>	1-22
A	<p>----- GB 2 079 755 A (OTSUKA PHARMA CO LTD) 27 January 1982 (1982-01-27) page 1, lines 5-9 claim 1</p>	1-22
A	<p>----- GB 2 137 206 A (GLAXO GROUP LTD) 3 October 1984 (1984-10-03) page 1, lines 28-36 claim 1</p>	1-22
A	<p>----- GB 1 384 372 A (GLAXO LAB LTD) 19 February 1975 (1975-02-19) page 1, left-hand column, line 11 - page 2, left-hand column, line 19 claim 1</p> <p>-----</p>	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/007819

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0200679	A	03-01-2002	AU 8389101 A BR 0112068 A CA 2412541 A1 CN 1439018 T CZ 20024203 A3 WO 0200679 A2 EP 1299409 A2 HU 0300783 A2 JP 2004501930 T NO 20026253 A PL 358428 A1 SK 18132002 A3 US 2003158163 A1 ZA 200300202 A	08-01-2002 01-04-2003 03-01-2002 27-08-2003 16-04-2003 03-01-2002 09-04-2003 28-07-2003 22-01-2004 18-02-2003 09-08-2004 05-08-2003 21-08-2003 15-10-2003
GB 1514476	A	14-06-1978	AU 8440475 A BE 832889 A1 CH 612686 A5 DE 2538595 A1 DK 389175 A ,B, FR 2282899 A1 IE 41663 B1 JP 51048649 A NL 7510226 A SE 405976 B SE 7509651 A US 4093721 A ZA 7505553 A	03-03-1977 01-03-1976 15-08-1979 11-03-1976 01-03-1976 26-03-1976 27-02-1980 26-04-1976 02-03-1976 15-01-1979 01-03-1976 06-06-1978 29-09-1976
US 3856828	A	24-12-1974	GB 1438940 A AU 473714 B2 AU 5825273 A BE 802481 A4 CA 1034565 A1 CH 619968 A5 DE 2336633 A1 DK 133158 B ES 417012 A2 FR 2192840 A2 IE 37925 B1 IL 42779 A JP 1163743 C JP 49080058 A JP 57050800 B LU 68039 A1 NL 7309992 A PH 14795 A SE 396079 B ZA 7304896 A	09-06-1976 01-07-1976 23-01-1975 18-01-1974 11-07-1978 31-10-1980 31-01-1974 29-03-1976 16-04-1976 15-02-1974 09-11-1977 29-04-1977 26-08-1983 02-08-1974 28-10-1982 26-09-1973 22-01-1974 09-12-1981 05-09-1977 24-12-1974
WO 8903390	A	20-04-1989	WO 8903390 A1 AT 90355 T DE 3786174 D1 EP 0334853 A1	20-04-1989 15-06-1993 15-07-1993 04-10-1989
GB 2079755	A	27-01-1982	AT 379817 B AT 265684 A AT 379816 B	10-03-1986 15-07-1985 10-03-1986

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/007819

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB 2079755	A	AT 307081 A	15-07-1985
		AU 540898 B2	06-12-1984
		AU 7259181 A	14-01-1982
		BE 889563 A1	03-11-1981
		CA 1174667 A1	18-09-1984
		CH 648856 A5	15-04-1985
		DE 3126732 A1	25-03-1982
		DK 302181 A , B,	11-01-1982
		ES 8300785 A1	01-02-1983
		ES 8306767 A1	16-09-1983
		FI 812175 A , B,	11-01-1982
		FR 2486529 A1	15-01-1982
		IT 1205446 B	23-03-1989
		JP 1011037 B	23-02-1989
		JP 1530924 C	15-11-1989
		JP 57045200 A	13-03-1982
		KR 8600266 B1	22-03-1986
		NL 8103315 A , B,	01-02-1982
		NO 812344 A , B,	11-01-1982
		PH 25874 A	02-12-1991
		PT 73348 A , B	01-08-1981
		SE 449106 B	06-04-1987
		SE 8104132 A	11-01-1982
		SU 1318169 A3	15-06-1987
		US 6610675 B1	26-08-2003
		US 4710495 A	01-12-1987
		US 4996335 A	26-02-1991
		ZA 8104440 A	27-10-1982
GB 2137206	A	03-10-1984	
		AT 395428 B	28-12-1992
		AT 17084 A	15-05-1992
		AT 401521 B	25-09-1996
		AT 34491 A	15-02-1996
		AT 395427 B	28-12-1992
		AT 67481 A	15-05-1992
		AT 395429 B	28-12-1992
		AT 203186 A	15-05-1992
		AU 544517 B2	06-06-1985
		AU 6729881 A	20-08-1981
		BE 887518 A1	13-08-1981
		BG 60700 B2	29-12-1995
		CA 1201114 A1	25-02-1986
		CA 1205464 A2	03-06-1986
		CH 644615 A5	15-08-1984
		CH 651307 A5	13-09-1985
		CZ 9104034 A3	16-03-1994
		CY 1291 A	18-10-1985
		DE 3105307 A1	10-12-1981
		DE 3153379 C2	19-11-1992
		DK 62381 A , B,	16-08-1981
		ES 8207194 A1	01-12-1982
		ES 8305379 A1	01-07-1983
		ES 8402317 A1	16-04-1984
		ES 8502447 A1	01-04-1985
		ES 8600936 A1	16-02-1986
		FI 810444 A , B,	16-08-1981
		FR 2477156 A1	04-09-1981
		FR 2485542 A1	31-12-1981

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP2004/007819

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
GB 2137206	A	GB 2088877 A , B	16-06-1982	
		HK 58385 A	16-08-1985	
		IE 51394 B1	24-12-1986	
		IE 51395 B1	24-12-1986	
		IT 1170717 B	03-06-1987	
		JP 1488353 C	23-03-1989	
		JP 56138200 A	28-10-1981	
		JP 63037120 B	22-07-1988	
		KE 3526 A	07-06-1985	
		KR 8500969 B1	02-07-1985	
		MX 9202717 A1	30-06-1992	
		MY 75785 A	31-12-1985	
		NL 84649 C		
		NL 960029 I1	03-02-1997	
		NL 8100707 A , B,	16-09-1981	
		NZ 196260 A	30-11-1983	
		PH 24267 A	29-05-1990	
		PT 72502 A , B	01-03-1981	
		SE 452468 B	30-11-1987	
		SE 8101010 A	16-08-1981	
		SG 36885 G	15-11-1985	
GB 1384372	A	19-02-1975	AU 473868 B2	08-07-1976
			AU 3811072 A	26-07-1973
			BE 778285 A1	20-07-1972
			CA 1003820 A1	18-01-1977
			CH 602786 A5	15-08-1978
			DE 2202691 A1	03-08-1972
			DK 132894 B	23-02-1976
			ES 399057 A1	01-11-1974
			FR 2122539 A5	01-09-1972
			HK 34278 A	07-07-1978
			IE 36000 B1	21-07-1976
			IL 38589 A	30-06-1976
			JP 56011720 B	16-03-1981
			MY 30878 A	31-12-1978
			NL 7200818 A , B,	24-07-1972
			NO 137321 B	31-10-1977
			SE 383522 B	15-03-1976
			ZA 7200401 A	26-09-1973